REMARKS

Claims 1, 3-23 and 48-51 of the above-referenced application are currently under examination. Claims 2, 24-47 and 52-62 are withdrawn from consideration as being drawn to a non-elected invention and have been cancelled by this amendment. Further, claims 3-4, 6-23 and 48-51 are cancelled without prejudice. Claims 1 and 5 have been amended. Claims 63-104 are new.

Support for amended claims:

Support for the amendments to the claims 1 and 5 is found, *inter alia*, throughout the specification as originally filed. More particularly, support for the amendment to claim 1 is found in claim 1 as originally filed and has been amended to specify that the water insoluble polymer is a block copolymer comprising less than 50% hydrophilic blocks and greater than 50% hydrophobic blocks. Support for these amendments is found in claim 3 presently on file and at page 13, lines 7-9. Support for the amendment to claim 5 is found in claim 5 as originally filed.

Support for the newly added claims:

Support for the newly added claims 63-104 is found, *inter alia*, throughout the specification as originally filed. More particularly, support for the newly added claims 63, 64, 65 and 66, is found in claims 3 and 6 as originally filed. Support for the newly added claims 67-79, is found in claims 7-15 presently on file. Support for the newly added claims 80-91 and 94-98, is found in claims 19-23 and 51 presently on file. Support for the newly added claims 92 and 93 relate to the specific triblock and MePEG formulation, for example as described at page 49, lines 14 and 15. Support for the newly added claims 99 and 100, is found in claims 17 and 18 presently on file. Support for the newly added claims 101 and 104, is found in claims 48-51 presently on file.

In view of the foregoing support, Applicants believe no new material has been introduced, and respectfully request that the Examiner enter the amendments and newly added claims.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

First Rejection Under 35 USC § 103(a)

Claims 1, 3-10, 13, 19-22 were rejected under 35 U.S.C. § 103(a), as being obvious and therefore unpatentable over Zhang *et al.* in view of Hunter *et al.* Applicants respectfully traverse the Examiner's rejection. In the portion of Hunter, *et al.* referred to by the Examiner, the authors described mixing paclitaxel with MePEG and blending with melted PCL, column 49, lines 28-32 of Hunter, *et al.* shows that the temperature of the melted PCL approached 65° C. Hunter, *et al.* indicates that this method avoids the use of the organic solvent used in other examples disclosed in Hunter, *et al.*

Zhang, *et al.* describes blending paclitaxel with a melted block copolymer at 60° C (page 200, last paragraph). No organic solvent or other dissolution aid was employed by Zhang, *et al.* Thus the blending temperature is similar to that used by Hunter, *et al.*, but in the case of Zhang, *et al.*, paclitaxel is dissolved directly into the block copolymer.

The person of skill in the art would not be motivated to combine the teachings of Hunter, *et al.* with Zhang, *et al.*, as suggested by the Examiner, since there is no indication of any difficulty in dissolving paclitaxel in the copolymers disclosed by Zhang, *et al.* Thus, there would be no motivation to follow any suggestion by Hunter, *et al.* to employ MePEG to assist in dissolving paclitaxel. Therefore, Zhang *et al.* in view of Hunter *et al.* does not make the invention obvious. Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

Second Rejection Under 35 USC § 103(a)

Claims 1, 3-23, 48-51 were rejected under 35 U.S.C. § 103(a), as being obvious and therefore unpatentable over Cha *et al.* '717 in view of Hunter *et al.*. Applicants respectfully traverse the Examiner's rejection. The block copolymers described in Cha, *et al.* '717 are water soluble and exhibit reverse gelation characteristics. The water soluble copolymers of Cha, *et al.*

contain 50% or more hydrophilic blocks (see col. 8, lines 19-35). The polymeric drug delivery system claimed in the instant application requires the presence of a water insoluble polymer. Cha, *et al.* does not disclose a water insoluble block copolymer comprising less than 50% hydrophilic blocks and greater than 50% hydrophobic blocks as recited in claim 1 as amended.

The water insoluble polymer component of the instant invention is different from any polymer described by Cha, *et al.* Cha, *et al.* is directed to producing liquid, aqueous, reverse gelation formulations (see abstarct and col. 9 lines 3-7). Thus, the person of skill in the art would not be motivated to combine the teachings of Cha, *et al.* with Hunter, *et al.* or expect the results of the instant invention. Accordingly, the enclosed claims are not obvious over Cha, *et al.* combined with any of the references cited by the Examiner. Applicants respectfully request that the second rejection under 35 U.S.C. § 103(a) also be withdrawn.

Rejection Under 35 USC § 112, first and second paragraphs

Claim 16 was rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification does not reasonably provide enablement for any triblock polymer of PEG and any mixture of glycolic acid, lactic acid and caprolactone.

Claims 16-18 and 48-51 were rejected under 35 U.S.C. § 112, second paragraph, for the reason that alkylene glycol can not be a monomer for the B block.

Applicants respectfully traverse the Examiner's rejections. Claims 16-18 and 48-51 have been cancelled.

We thank the Examiner for commenting on the clarity of claims 16-18 and 48-51 with respect to the B block, although we note that a polyalkylene oxide such as polyethylene glycol may be formed from the polymerization of either an alkylene oxide or an alkylene glycol. Nevertheless, newly added claims 99-100 and 101-104, which are based on claims 17-18 and 48-51 originally filed specify that the B block is a polyalkylene oxide, rather than defining the B block by reference to polymerization of monomers. .

It is believed that the Examiner's rejections under 35 U.S.C. 112 (first and second paragraphs) with respect to claims 16-18 and 48 have been met. Applicants respectfully request that the rejection under 35 U.S.C. 112 (first and second paragraphs), be withdrawn.

Request for References

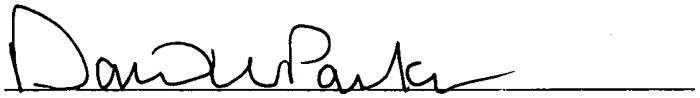
The Examiner indicated that incomplete copies of Deng *et al.* and Youxin *et al.* were recorded with the previously filed Information Disclosure Statement and also requests the references Martini *et al.*, Ramaswamy *et al.* and Zhang *et al.*. The Applicants enclose copies of the above 5 references with a Supplemental Information Disclosure Statement submitted herewith.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. Applicants respectfully request the issuance of a timely Notice of Allowance.

Respectfully submitted,

Seed Intellectual Property Law Group PLLC



David W. Parker
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Enclosure(s):
Postcard
(Fourth) Supplemental Information Disclosure Statement (Form PTO-1449)
5 References (as noted above)

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

Claims 2-4 and 6-62 have been cancelled.

Claims 63-104 have been added.

Claims 1 and 5 have been amended as follows:

1. (Amended) A polymeric drug delivery system, comprising:

a) a biodegradable water insoluble block copolymer that is a solid or wax at 37° C, comprising greater than 50% hydrophobic blocks, and less than 50% hydrophilic blocks;

b) a biodegradable water soluble polymer that is a liquid at 25° C; and,

c) a hydrophobic drug,

wherein said polymeric drug delivery system is a liquid or paste at 25° C.

5. (Amended) The polymeric drug delivery system of claim 1, wherein said water insoluble block copolymer is a triblock copolymer having the formula ABA, wherein each A is a hydrophobic block, and wherein B is the hydrophilic block.